

Appl. No. 09/097,023
Response AF dated January 14, 2005
Reply to Final Office Action of November 16, 2004

REMARKS

Applicants have carefully reviewed the Final Office Action dated November 16, 2004. Claims 1-15, 17-22, 24-42, 44-48, 50-56, 58, 59, and 61-63 are pending in the application, wherein, claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 stand rejected and claims 51 and 52 are objected to. The following remarks are submitted in response to the Final Office Action.

Objections

The drawings are objected to under 35 U.S.C. §132 because the Examiner asserts they introduce new matter into the disclosure. Specifically, Figure 5 is objected to as showing new matter of a braid (210) that is spaced free from the inner and outer liners, and Figure 6 is objected to as showing new matter of a coil (216) that is established in contact with an inner liner, but free from the outer liner. Applicants respectfully traverse this objection. Applicants assert that no new matter has been added in the drawings and all figures find support in the disclosure as originally filed.

Applicants respectfully assert that claims 51 and 52 remain in their original form as filed. Claim 51 recites a catheter, wherein the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover. Claim 52 recites a catheter, wherein the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover. Support for the limitations of claims 51 and 52 may be located in the specification, as originally filed, for example at page 10, lines 1-10.

The Examiner asserts, "Applicant's disclosure of a braid 'interposed between' a liner and cover is not a disclosure of spacing on both sides or spacing on one side with contact on the other." Applicants respectfully disagree with this assertion. "During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." M.P.E.P. §2111.01, citing *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322. The Applicants assert the Examiner is impermissibly narrowing the terminology chosen by the Applicants in asserting Figures 5 and 6 introduce new matter. Contrary to the Examiner's assertion, the orientation of the stiffener (i.e., knit, braid, coil) is not intended to be restricted to a

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specific embodiment, but may be positioned at any location between an inner liner and an outer cover. As noted in the concluding paragraph of the specification at page 10, lines 16-18, "it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense." In establishing a disclosure, an applicant may rely on the specification, drawings or the original claims as filed. M.P.E.P. §608.04. Applicants assert Figures 5 and 6 sufficiently reflect an illustrative embodiment of what is claimed in claims 51 and 52 and supported by the specification as originally filed.

Applicants respectfully assert that no new matter has been added to the disclosure with the addition of Figures 5 and 6 and the accompanying description in the specification. Withdrawal of this objection is respectfully anticipated.

§102 Rejections

Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 05-220225 in view of Samson (U.S. Patent No. 5,702,373). The Examiner asserts JP 05-220225 shows a knitted reinforcing metal member 35 with an inner liner and outer cover, wherein Samson is relied upon for description of the JP 05-220225 document. Applicants respectfully traverse this rejection.

In directing the Examiner to Applicants' remarks regarding the deficiencies of the JP 05-220225 reference discussed in the previous Response filed on August 13, 2004, Applicants renew their assertion that JP 05-220225 fails to disclose each and every element of the invention required to anticipate the rejected claims of the current invention. Although the English language Abstract of JP 05-220225 uses the term "knitted," Applicants assert JP 05-220225 fails to teach a knitted member as claimed in the current application. Additionally, Applicants traverse the Examiner's assertions that further limitations of the rejected claims are inherently present in the JP 05-220225 reference.

The Examiner appears to rely solely on the word "knitted" used in the Abstract of JP 05-220225 without further evaluation of the reference. The Examiner asserts "[t]he dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention," while rejecting any reliance on the drawings as "a tortuous exercise that is inconclusive and clearly

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misleading" since the "sketchy figures...lack the appropriate details to accurately discern the elemental structure." Applicants disagree with the Examiner's reliance on the word "knitted" without construing the term in view of the specification and the accompanying drawings. A reference cannot anticipate a claim "by possessing identically named parts," unless those parts also "have the same structure or otherwise satisfy the claim limitations, and were understood to function in the same way by one skilled in the art." *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998). Applicants assert the layer taught in JP 05-220225 and shown in Figures 4-7 does not have the same structure as the knitted member of the current invention; therefore, the reference fails to anticipate the current claims. The Examiner's sole reliance on the word "knit" and failure to recognize the structural differences shown in the drawings in upholding the rejection are without merit.

Applicants assert that JP 05-220225 at least fails to teach a member formed from a plurality of interlocking up loops and down loops or a knit member generally not radially expandable. The Examiner's assertions that "the dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention" and "the knitted nature of the member would inherently make the member generally not radially expandable" are without merit. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic." M.P.E.P. §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). As previously asserted, the term "knitted" has multiple definitions. The Merriam-Webster Online Dictionary (obtainable at www.m-w.com) states "knit" may mean: (1) to tie together; (2) to link firmly or closely; or (3) to form by interlacing yarn or thread in a series of connected loops with needles. The fact that the term "knit" has multiple meanings in view of the Figures of the JP 05-220225 reference which clearly don't show a member formed from a plurality of interlocking up loops and down loops rebuts any attempt by the Examiner to claim the limitations are inherently present in the prior art reference. Adopting the Examiner's assertion, without conceding the correctness of the statement, that "the figures lack the appropriate details

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to accurately discern the elemental structure," how can the Examiner make a definitive assertion that JP 05-220225 discloses a knit member formed from a plurality of interlocking up loops and down loops if "knit" can have multiple definitions and the Examiner fails to construe the term in view of the specification and/or the drawings? Additionally, a knitted member, such as the knitted middle layer 23 taught in Cook, U.S. Patent No. 4,637,396, may be expandable. Therefore, a knitted member is not necessarily not radially expandable as the Examiner erroneously concludes in asserting the limitation is inherent in the prior art. Because these limitations are not necessarily taught by the JP 05-220225 reference, Applicants assert the inherency argument is without merit, and JP 05-220225 fails to teach each and every element of the claimed invention.

As the English language Abstract of JP 05-220225 does not teach all the structural limitations of the claimed invention such as a non-radially expandable tubular member formed of interlocking up and down loops, it fails to teach each and every element of the invention as claimed in claims 1, 24 and 31. Applicants firmly believe claims 1, 24 and 31 are in condition for allowance. Claims 2, 13, 19 and 20 depend from claim 1 and contain significant additional elements; claim 27 depends from claim 24 and contains significant additional elements; and claims 40, 46, 47, 50, 53-56, 58 and 59 depend from claim 31 and contain significant additional elements. Applicants firmly believe that these claims are in condition for allowance for at least the reasons stated above.

Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 stand rejected under 35 U.S.C. §102(e) as being anticipated by Leoni (U.S. Patent No. 5,772,681). The Examiner asserts that Leoni describes a catheter having a knitted reinforcing member of nitinol between an inner liner and outer cover that is generally not expandable in the section adjacent to the balloon section and "the up and down loops of the knitted member is inherent in view of the dictionary definition of knitted." Applicants respectfully traverse this rejection.

Directing the Examiner to remarks submitted in the previous Response filed August 13, 2004, regarding the deficiencies of Leoni, Applicants respectfully assert Leoni at least fails to teach a knit tubular member formed from a plurality of interlocking up loops and down loops that is generally not radially expandable. Leoni teaches a dilation catheter having an expandable balloon section. The balloon section has a reinforcement net made of metallic monofilaments

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extending helically around the longitudinal axis of the balloon section and moveable with respect to each other at the crossover points to allow expansion of the balloon section. The reinforcement net may be wound, braided or knitted.

Although Leoni teaches a reinforcing net comprising metallic monofilaments that may be helically wound, braided, or knitted, Leoni's teachings must be read in light of the specification. Identically named parts in a prior art reference must have the same structure or otherwise satisfy the claim limitations in order to anticipate. See *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998). As discussed above and in an earlier response, the Merriam-Webster Online Dictionary (obtainable at www.m-w.com) contains multiple definitions for the word "knitted." There are at least three plain meanings of "knit" including (1) to tie together; (2) to link firmly or closely; and (3) to form by interlacing yarn or thread in a series of connected loops with needles. Given the different plain meanings possible for "knit," the skilled artisan would logically turn to the remainder of the specification and accompanying figures in the reference in an attempt to determine which meaning of "knit" was intended by the reference. It is apparent from a close examination of Leoni that the definition of "knitted" relied on in Leoni is not the same as is intended in the current application. Leoni teaches a reinforcing net made of metallic monofilaments wherein the contact points of the mesh rows are moveable with respect to each other in the crossover points. See column 3, lines 55-60. The limitation that the reinforcing net includes mesh rows extending helically around the longitudinal axis, wherein the mesh rows are moveable with respect to each other in the crossover points is equally limiting for a knitted reinforcing net as it is for a braided reinforcing net as taught in Leoni. See column 6, lines 16-34. Claim 6 of Leoni states in part, "wherein said reinforcement net (2) is a knitted net of metallic monofilaments, mesh rows of said net extending helically around the longitudinal axis of the middle section...wherein said mesh rows are moveable with respect to each other in the crossover points (5) during expansion of the balloon section." Thus, the reinforcement net disclosed in Leoni does not have the same structure or otherwise satisfy the claim limitations of the current claims. The crossover points 5 are not points of interlocking loops, but are points wherein the mesh rows are moveable with respect to each other. It follows that the definition of "knit" relied on by Leoni is different from the definition intended in the current application. Further, the structure of the reinforcing mesh

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of Leoni is distinctively dissimilar from the structure of the knitted member of the current invention. Therefore, Leoni fails to teach what is claimed in the current application, namely, a knit tubular member formed from a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable.

Applicants traverse the Examiner's assertion that "[t]he up and down loops of the knitted member is inherent in view of the dictionary definition of knitted." As stated above, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). It is clear that the missing descriptive matter (i.e., the interlocking up and down loops of the knitted member) is not necessarily present in the reinforcement mesh described in Leoni. The multiple dictionary definitions for knit as well as the description and accompanying drawings describing the reinforcement net of Leoni demonstrate that not only is the claimed limitation not necessarily present in the reference, but the reference actually teaches a knit member having a dissimilar structure (i.e., the mesh rows of the knitted net are moveable with respect to each other at the crossover points) than the one currently claimed. Therefore, the inherency argument relied on by the Examiner lacks merit and Leoni fails to anticipate the claimed invention.

Applicants respectfully assert that claims 1, 24 and 31 contain at least one element not taught in Leoni. Therefore, they are believed to be in condition for allowance. Claims 2-5, 13, 14, 18-20 and 54-56 depend from claim 1 and contain significant additional elements, claims 25-27 depend from claim 24 and contain significant additional elements, and claims 32, 33, 40, 41, 45-47, 50, 53, 58 and 59 depend from claim 31 and contain significant additional elements. Therefore, these claims are also believed to be in condition for allowance.

§103 Rejections

Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) in view of Cox (U.S. Patent No. 5,257,974). The Examiner asserts that Cook discloses a catheter section having an elongate knit tubular multifilament member 23 made of interlocking up and down loops having an inner liner 22 and outer cover 24 and radiopaque

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markers, wherein the catheter section is made so that it only expands to a predetermined diameter. The Examiner further asserts that Cox teaches a multi-layered catheter that is made for predetermined expansion of less than 2.7%, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cox in the catheter of Cook. Applicants respectfully traverse this rejection.

In directing the Examiner to Applicants' arguments provided in the previous Response regarding the improper combination of Cook and Cox, Applicants renew their assertion that no *prima facie* case of obviousness may be established with the combination of cited references. Notwithstanding the fact that Cook teaches a significantly different apparatus from the current invention, namely an expandable balloon having a reinforcing layer to prevent overinflation and potential bursting of the balloon, there is no suggestion or motivation to take the expandable knitted member in Cook and combine it with the teachings of Cox. Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness using the stated prior art combination. In making the assertion, Applicants respectfully note that hindsight is impermissible, and the Examiner must base his obviousness rejection on the teachings found in the references, not what is taught in the present application.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation for combining the teachings of the references found in the prior art. M.P.E.P. §706.02(j). "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, quoting *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Contrary to the Examiner's assertion that Cook provides motivation to make the modification to the present invention, there is no motivation or suggestion to combine the teachings of Cook with the teachings of Cox required to establish *prima facie* obviousness. It is apparent that any modification of Cox or Cook with the teachings of the other would make the prior art invention unsatisfactory for its intended purpose.

Cook teaches a balloon catheter having a balloon reinforced by a knitted layer comprising elastic and inelastic plies. Column 3, lines 10-15. The knitted middle layer 23, as shown in Figure 2, is an interior layer of the balloon positioned between the inner layer 22 and the outer layer 24. By using elastic plies, the knitted layer is expandable, and the knitted layer is chosen

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for its expansion and contraction characteristics. Column 3, lines 45-48. Therefore, the expandable knitted layer imbedded in the balloon allows the balloon to expand to a predetermined diameter.

Cox, on the other hand, teaches an adapter for use with balloons of intravascular balloon catheters. The adapter, which may be placed about the exterior of the balloon, is preferably made of a material providing radial rigidity to the adapter, and serves to restrict the balloon's radial size. Column 5, lines 41-44. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See column 8, lines 31-34. The woven support structure is included in order to enhance the radial rigidity of the adapter. See column 8, lines 44-45. It is clear that any support structure added to the adapter of Cox is intended to provide enhanced rigidity to the adapter to reduce radial expansion.

Applicants assert that modifying the Cook reference with the woven support structure suggested in Cox would impart undesired rigidity into the balloon of Cook and prevent desired expansion of the balloon, therefore making the modified invention unsatisfactory for its intended purpose. Likewise, modifying Cox with the expandable knitted member taught in Cook would impart undesired expansion to the adapter taught in Cox. The expandable knitted member would not aid in enhancing the radial rigidity of the adapter; therefore, the proposed modification would not improve the performance of the adapter taught in Cox. Because such a proposed modification of either reference would render the prior art invention unsatisfactory for its intended purpose, Applicants assert there is no motivation to combine the teachings of Cox and Cook.

Additionally, but relatedly, the teachings of Cook and Cox actually teach away from one another. Cook teaches that an expandable balloon having a knitted layer is superior to prior known fabric reinforced balloons because,

Prior known balloons reinforced with a braided or woven fabric tube are unable to expand in diameter without correspondingly decreasing in length. However, a balloon reinforced with the knitted fabric tube described herein is capable of expanding three-dimensionally such that an increase in diameter does not require a decrease in length of the balloon.

Column 3, lines 48-55 (emphasis added). Therefore, Cook actually teaches away from the teachings of Cox. Applicants reject the Examiner's assertion that "this teaching is actually the

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motivation to make the modification." The language of Cook cited above would discourage one from substituting a woven or braided member for the knitted member of Cook. Additionally, Cox teaches adding a support structure 102 to enhance the radial rigidity of the adapter. However, the knitted layer of Cook is capable of expanding three-dimensionally; therefore, such a knitted layer taught in Cook would not provide the desired radial rigidity which the added support structure of Cox is intended to provide.

In other words, the prior art references actually teach away from one another, and modifying one reference in view of the teachings of the other would render the modification unsatisfactory for its intended purpose. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. §2141.02 (emphasis in original). Therefore, in view of the express teachings of the references, there is no motivation or suggestion to combine the teachings of Cook with those of Cox and the references actually teach away from one another. Applicants assert no *prima facie* case of obviousness has been established with this combination.

Applicants respectfully assert that no *prima facie* case of obviousness has been established as to claims 1 and 31 in view of the teachings of Cook and Cox. Therefore, it is requested that this rejection be withdrawn. Claims 1 and 31 are believed to be in condition for allowance. Claims 8-10, 13, 15, 18-21, 54-56 and 61 depend from claim 1 and contain significant additional elements and claims 36-38, 40, 42, 45-48, 50, 53, 58, 59 and 63 depend from claim 31 and contain significant additional elements. Therefore, these claims are also believed to be in condition for allowance.

Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) and Cox (U.S. Patent No. 5,257,974) in view of Leoni (U.S. Patent No. 5,772,681). The Examiner asserts that Cook and Cox disclose the claimed invention except for using nitinol as the knitted layer, and Leoni teaches using nitinol as the knitted layer to restrict expansion as a reinforcing layer. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Leoni with the device of Cook and Cox. Applicants respectfully traverse this rejection. As stated above, a *prima facie* case of obviousness has not been established with respect to the stated combination of prior art references. The inclusion of

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Leoni in the combination of references fails to provide disclosure necessary to establish a *prima facie* case, noting the deficiencies of Leoni as a reference as discussed above. Applicants respectfully request the rejection be withdrawn and assert that claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are in condition for allowance.

Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni (U.S. Patent No. 5,772,681) and further in view of Andersen et al. (U.S. Patent No. 5,674,276). The Examiner asserts that JP 05-220225 or Leoni disclose the claimed invention except for using multifilaments with first and second materials of a metal and a polymer. The Examiner asserts that Andersen et al. teach using multifilaments with first and second materials of a metal and a polymer, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of JP 05-220225 or Leoni with the teachings of Andersen et al. Applicants respectfully traverse this rejection. As explained above, neither JP 05-220225 nor Leoni teach the claimed invention, and Andersen et al. fail to remedy the shortcomings of JP 05-220225 and Leoni. For the reasons stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Claims 17, 22, 44 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni (U.S. Patent No. 5,772,681) in view of Jang et al. (U.S. Patent No. 4,898,591). The Examiner asserts that JP 05-220225 or Leoni disclose the claimed invention except for the materials of construction of the inner and outer liner and cover respectively. The Examiner asserts that Jang et al. teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, and it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of JP 05-220225 or Leoni. Applicants respectfully traverse this rejection. As explained above, neither JP 05-220225 nor Leoni teach the claimed invention, and Jang et al. fail to remedy the shortcomings of JP 05-220225 and Leoni. For the reasons stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Claims 17, 22, 44 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) and Cox (U.S. Patent No. 5,257,974), and further in view of Jang et al. (U.S. Patent No. 4,898,591). The Examiner asserts that Cook and Cox disclose the

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claimed invention except for a polyethylene inner and outer liner and cover. The Examiner asserts that Jang et al. teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang et al. in the invention of Cook and Cox to teach the claimed invention. Applicants respectfully traverse this rejection. As stated above, a *prima facie* case of obviousness has not been established by combining the teachings of Cook and Cox. Jang et al. fail to remedy this shortcoming. Thus no *prima facie* case of obviousness has been established with the combination of references. Applicants respectfully request the rejection be withdrawn and assert that claims 17, 22, 44 and 48 are in condition for allowance.

Conclusion

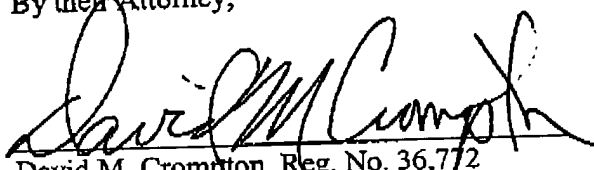
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Jill McFadden et al.

By their Attorney,

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